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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,480	05/19/2000	Gregory A Kopia	CRD-850	1106

7590 03/11/2003

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EXAMINER	
FERKO, KATHRYN P	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/575,480	Applicant(s) KOPIA ET AL.	
	Examiner Kathryn Ferko	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *2 and 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment/Arguments

This is a response to the amendment dated February 13, 2003. Claims 1 and 3-9 are pending.

1. Applicant's arguments with respect to claims 1 and 3-9 have been carefully reviewed and noted but are not considered persuasive.

Morris et al. do disclose treating restenosis and include an anti-inflammatory agent, where Cyclosporin A is known to have anti-inflammatory effects, and an antiproliferative agent as claimed. Further, Ragheb discloses using a combination of agents, including an anti-inflammatory agent and an anti-proliferative, see column 3, lines 54-67 and column 4, lines 56-67. Additionally, End teaches the ras inhibitor R11577 and Levitzki et al. teach tyrphostin and there is clear motivation to include those particular drugs in the system of Ragheb et al. although not explicitly recited. It is very well known in the art to coat stents with drugs. Therefore, given that R11577 increases antiproliferation and tyrphostin suppresses SMC, it would be obvious when treating restenosis to coat the stents with those particular drugs. Additionally, Ragheb et al. state that "a wide range of other bioactive material can be employed including, but not limited to,..." and it impossible and lengthy to list every one.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claim 1 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al. in US Patent No. 5,516,781.

Morris et al. disclose a method for treating of restenosis via intravascular infusion or delivery by release from a surface of a stent of a combination of at least two agents, including an anti-proliferative agent for inhibiting smooth muscle cell growth and an anti-inflammatory agent for inhibiting smooth muscle cell growth, in therapeutic dosage amounts, wherein Cyclosporin A is known to have anti-inflammatory effects, as recited in column 4 and claims 1-5.

4. Claim 1 and 3-4 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Ragheb et al. in US Patent No. 6,299,604.

Ragheb et al. disclose a process for the treatment of restenosis via intravascular infusion or delivery by release from a surface of a stent of a combination of at least two agents, including an anti-proliferative agent for inhibiting smooth muscle cell growth and an anti-inflammatory for inhibiting smooth muscle growth in therapeutic dosage amounts, as recited in column 2, lines 40-67, column 3, lines 54-67, column 4, column 7, lines 62-67, column 8, and column 9; an anti-inflammatory agent that is dexamethasone and an anti-proliferative that is taxol, as recited in column 9, lines 45-55; and a combination of a growth factor and an anti-proliferative, as recited in column 9, lines 50-60 and column 21, lines 45-55, and column 4, lines 55-60, wherein any combination of bioactive materials can be employed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of End.

Ragheb et al. disclose the invention as applied to claims 1. However, Ragheb et al. do not explicitly recite R11577. On the other hand, End teaches the ras inhibitor, R11577. Therefore, it would be obvious to one with ordinary

skill in the art modify the invention of Ragheb et al. to include R115777 as a signal transduction inhibitor for the purpose of increasing antiproliferation.

7. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Levitzki et al. in US Patent No. 5,932,580.

Ragheb et al. disclose the invention as applied to claim 1. However, Ragheb et al. do not explicitly recite tyrphostin as a tyrosine inhibitor. However, Levitzki et al. teach of tyrphostin, as recited in column 5, lines 35-67, column 6, and column 8. Therefore, since implantation is a method of administration as recited in column 8, line 67, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Ragheb et al. to include a the tyrosine inhibitor of tyrphostin to suppress SMC.

8. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Nagler et al. in US Patent No. 6,159,488.

Ragheb et al. disclose the invention as applied to claims 1and 3-4. However, Ragheb et al. do not explicitly recite halofuginone as an inhibitor of extracellular matrix. On the other hand, Nagler et al. teach a stent coated with halofuginone, as recited in column 9 and column 10. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the system of Ragheb et al. to include halofuginone for the purpose of inhibiting SMC proliferation.

D uble Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 and 3-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 25 of copending Application No. 09/850,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for identical subject matter. In some aspects some limitations are broader while others are more specific.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

Henry Bennett
Supervisory Patent Examiner
Group 3700

KF
March 1, 2003